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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/606,910	06/29/00	KARSTEN U	0107-027P

EXAMINER	
TRAN, M	
ART UNIT	PAPER NUMBER
1642	12

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Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trad marks

Office Action Summary	Application No.	Applicant(s)	
	09/606,910	KARSTEN ET AL.	
	Examiner	Art Unit	
	MAU T TRAN	1642	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *30 March 2001* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *8-14* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☒ Claim(s) *8-14* is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☒ Claim(s) *8 and 14* is/are objected to.

8)☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *29 June 2000* is/are objected to by the Examiner.

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

13)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

15)☒ Notice of References Cited (PTO-892)
16)☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
17)☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
18)☐ Interview Summary (PTO-413) Paper No(s). _____ .
19)☐ Notice of Informal Patent Application (PTO-152)
20)☐ Other: .

DETAILED ACTION

This application is a CON of PCT DE 98/03819 filed December 30, 1998. Preliminary amendment was received on October 23, 2000 in which original claims 1-7 were cancelled and replaced with new claims 8-14. Claims 8-14 are pending and are examined on the merits.

Priority

1. Receipt is acknowledged of papers submitted under 35 U.S.C. 119(a)-(d), which papers have been placed of record in the file.

2. An application in which the benefits of an earlier application are desired must contain a specific reference to the prior application(s) in the first sentence of the specification (37 CFR 1.78).

It is suggested that Applicant puts "This Application is a CON of PCT DE98/03819 filed December 30, 1998" on the first line of the specification to fulfill priority requirements under 35 USC 120.

Drawings

3. The drawings are objected to because the figures are labeled in a foreign language that cannot be read by the Examiner. The drawings should be properly labeled in English. Correction is required.

Specification

4. The abstract of the disclosure is objected to because the word "length" is misspelled. Correction is required. See MPEP § 608.01(b).

Claim Objections

5. Claims 8 and 14 are objected to because of the following informalities:

Claim 8, line 1, the word "length" is misspelled.

Claim 14, line 2, the word "active" is misspelled. Appropriate correction is required.

Claim Rejections - 35 USC § 112

6. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the

art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 8-14 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for synthetic peptide consisting essentially of PDTRPAP region of MUC1 wherein the threonine is glycosylated, does not reasonably provide enablement for a vaccine comprising peptides of differing length with glycosylation of mostly but not exclusively threonine of MUC1. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

Claims 8-14 are drawn to a tumor vaccine comprising of the PDTRPAP region of MUC1 of at least 20 amino acids which is glycosylated and a process for combating tumor cells.

The specification disclosed an amino acid sequence consisting of PDTRPAP region that is glycosylated specifically at threonine wherein this antigen is immunogenic and can be used as a vaccine. However, there is no clinical data to show that any length of MUC1 being glycosylated at any region along the PDTRPAP can work as an immunogenic vaccine other than by what is disclosed by ELISA (pg. 4 of the specification). Vaccine therapy using peptides is very specific and requires specific disclosure of specific sequences and modification of the sequences to induce immunogenicity in the host. It is well known in the art that cancer treatment in vivo is a complex process in which the individual's immune response and the host-tumor relationship have to be considered. It is well known in the art that cancer treatment in vivo is a complex process in which the individual's immune response and the host-tumor relationship have to be considered. It is clear that all immune systems are not alike and the pathology, etiology and nature of the disease have to be considered individually (see Osband et al, Immunology Today, 1990, Vol. 11, pg. 193-195, specifically abstract and pg. 193, first column). Therefore, though a drug is able to work in an in vitro environment, it does not necessarily guarantee the success of the therapy

in vivo or that if the method of treating the cancer would even reach the tumor. The complexities of the human body is in no way represented by a petri dish and a cell culture and cannot be assessed without extensive experimentation.

The specification provides insufficient guidance with regard to the issues raised above and provides no working examples which would provide guidance to one skilled in the art and no evidence has been provided which would allow one of skill in the art to predict the efficacy of the claimed methods with a reasonable expectation of success. In view of the above, one of skill in the art would be forced into undue experimentation to practice the claimed invention.

7. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 8-14 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 8 recites the terms "differing length" without further defining what length is appropriate or without further limitation on the length that is being claimed.

Claim 14 recites the term "patient in need" without further defining what patient is in need of therapy. How can one of ordinary skill discern when a patient is in need of therapy requiring a tumor vaccine of MUC1 antigen? It is not clear what is being claimed.

Further clarification is required or removal of these terms from the claim language is appropriate.

Claim Rejections - 35 USC § 102

8. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 8-13 are rejected under 35 U.S.C. 102(b) as being anticipated by Hanisch et al (Cancer Res., 1995, Vol. 55(18):4036-40, abstract) or Taylor-Papadimitriou et al (WO/05142, May 17, 1990, see claims 1-4).

Claims 8-13 are drawn to a vaccine tumor comprising a MUC1 peptide PDTRPAP of at least 20 amino acids in length wherein the peptide is glycosylated by a monosaccharide or a short-chain oligosaccharide by GalNAc or GalB-1,3GalNAc. However, claims 8-13 are drafted as product claims directed towards the amino acid of PDTRPAP glycosylated at the threonine position with an intended use of being a tumor vaccine. Since these are drafted as product claims with an intended use, the use is given little weight upon interpretation of the claims by the Examiner.

Hanisch et al taught a MUC1 glycosylated amino acid sequence that is glycosylated by GalNAc1 (using an oligosaccharide) that is less than 20 amino acids in length, thereby anticipating the claims.

Taylor-Papadimitriou et al taught an amino acid sequence that is glycosylated by GalNAc that is less than 20 amino acids in length (see claims 1-4 especially), thereby anticipating the claim.

9. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

Claims 8-13 are rejected under 35 U.S.C. 102(e) as being unpatentable by McKenzie et al US 5989552 (filed April 9, 1997).

Claims 8-13 are drawn to a vaccine tumor comprising a MUC1 peptide PDTRPAP of at least 20 amino acids in length wherein the peptide is glycosylated by a monosaccharide or a short-chain oligosaccharide by GalNAc or GalB-1,3GalNAc. However, claims 8-13 are drafted as product claims directed towards the amino acid of

PDTRPAP glycosylated at the threonine position with an intended use of being a tumor vaccine. Since these are drafted as product claims with an intended use, the use is given little weight upon interpretation of the claims by the Examiner.

McKenzie et al taught a MUC1 peptide that is glycosylated by GalNAc by an oligosaccharide of PDTRPAP and less than 20 amino acids in length (see claims 1-7), thereby rendering the claims unpatentable.

Conclusion

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Mau Tran whose telephone number is 703-605-1165. The examiner can normally be reached on Monday-Friday from 8:00 a.m. – 5:30 p.m. with alternate Mondays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anthony Caputa can be reached on 703-308-3995. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1234.

Mau Tran, Ph.D.
Patent Examiner, Art Unit 1642
June 12, 2001

GEETHA P. BANSAL
PRIMARY EXAMINER